

Nonfinal Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claims 2 and 8-13 under 35 USC 112, first paragraph is made moot by the cancellation of the instant claims.

3. The rejection of claims 1, 3-7 and 14-16 under 35 USC 112, first paragraph is withdrawn.

Claim Rejections - 35 USC § 103

4. The rejection of claims 2 and 8-13 under 35 USC 103(a) over Cherukuri et al. (US 6,344,222) in view of McCullough et al. (US 6,495,605) as evidenced by Eswara et al. (US 5,780,051), and further in view of Hanauer (Gut, 2002, Vol. 51, pp. 182-183) is made moot by the cancellation of the instant claims.

5. The rejection of claims 1, 3-7 and 14-16 under 35 USC 103(a) over Cherukuri et al. (US 6,344,222) in view of McCullough et al. (US 6,495,605) as evidenced by Eswara et al. (US 5,780,051), and further in view of Hanauer (Gut, 2002, Vol. 51, pp. 182-183) is withdrawn.

6. Claims 1, 3-7 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (US 6,344,222), Spero et al. (US 2003/0008844), Hanauer (Gut, 2002, Vol. 51, pp. 182-183) and Gabry et al. (Mol. Psychiatry, 2002, Vol. 7, pp. 474-483) in combination.

Briefly, the instant claims are drawn to a method of treating ulcerative colitis comprising administering a composition comprising nicotine and bupropion and optionally additional active ingredients.

Cherukuri et al. teaches nicotine therapy is beneficial in the treatment of ulcerative colitis (see col. 17, lines 53-60). The reference also teaches the nicotine composition can be administered orally (column 23, line 44).

Spero et al. teaches a composition comprising sulodexide for treatment of inflammatory bowel disease such as ulcerative colitis (see the entire article). The reference also teaches additional active ingredients including nicotine, mesalamine bupropion, etc. (see sections 0034, 0047, 0095 and claim 7) and various mode of administration including oral and transdermal administration (see section 0038).

Hanauer teaches the utilization of corticosteroids, such as budesonide, for the treatment of ulcerative colitis (see page 182).

Gabry et al. teaches the suppression of gastric ulceration by antidepressants (fluoxetine and bupropion), anxiolytics (diazepam and buspirone) or CRH-R1 antagonist (antalarmin) (see the entire article, especially Abstract).

Based on the knowledge in the art at the time of the present invention as evidenced by the above cited references, it would have been obvious to the skilled

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artisan in the art that nicotine, bupropion, mesalamine (mesalazine) and corticosteroids (such as hydrocortisone and budesonide) were useful in treating ulcerative colitis. The claimed composition is prima facie obvious because (a) each of the claimed active ingredients is known in the art to be useful in treating ulcerative colitis and (b) combination therapy is well known in the medical art. Additionally, the court has held that it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Claims 3 and 4 recite transdermal and oral administrations; claims 5 and 6 recite additional active ingredients; claim 7 recites administration for a period greater than six months and claims 14-16 recite specific dose ranges of nicotine and bupropion.

However, the art teaches (a) various routes of administration for the claimed compounds including oral and transdermal administration (see for example, Spero as discussed above) and (b) additional ulcerative colitis therapy such as mesalazine and budesonide (see Spero, Hanauer and Gabry as discussed above). Additionally, the determination of the duration and/or dosage needed to treat any condition, including ulcerative colitis, requires only routine experimentation which is done regularly in the medicine art. Therefore, the instant claims are prima facie obvious in view of the level of skill of ordinary artisan in the art at the time of the present invention.

Response to Arguments

7. Applicant argues Cherukuri neither discloses nor suggests the use of nicotine to treat ulcerative colitis and neither Cherukuri nor Hanauer teaches the combination of nicotine and bupropion to treat ulcerative colitis. Applicant also argues that based on the disclosure in the art, the combination of elements to treat colitis would not lead to predictable results and that studies has shown treatment with nicotine is patient dependent with unwanted side effects and bupropion demonstrates some negative side effects. Applicant's argument was considered but not persuasive for the following reasons.

Contrary to applicant's statement about Cherukuri, the reference states:

While the invention has been described with particular reference to smoking reduction or cessation, it is also within the scope hereof that the nicotine delivery system heretofore described also be utilized in the treatment of certain diseases as well. For example, recent studies have demonstrated that nicotine therapy can be particularly beneficial to persons with ulcerative colitis, Parkinson's disease, Tourette's syndrome and Alzheimer's disease as well.

(see col. 17, lines

53-60 of Cherukuri). Therefore, it teaches that in addition to its use in smoking reduction or cessation, it is also useful in treating certain diseases such as ulcerative colitis.

Secondly, the examiner agrees that neither Cherukuri nor Hanauer teaches the combination of nicotine and bupropion for treatment of ulcerative colitis. However, as discussed above in #6, the art teaches each is useful in treating ulcerative colitis and, thus, the combination would be prima facie obvious.

Lastly, applicant argues the art does not make obvious predictable results with the combination of nicotine and bupropion in the treatment of ulcerative colitis and that each drug has unwanted side effects. First, one of the major reasons for combination therapy is the utilization of less of each of the active ingredient and, thus, reduction in the side effect(s) caused by each ingredient within the composition. As to applicant's argument that studies has shown that treatment of nicotine is patient dependent, said is not a teaching away from the use of the drug to treat ulcerative colitis. In fact, it is well known in the medical art that therapeutic result(s) with any drug is patient dependent, i.e., results vary within the patient population.

For these reasons, applicant's arguments against Cherukuri and Hanauer were not persuasive.

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612